

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

WATSON LABORATORIES, INC.

Petitioner

v.

UNITED THERAPEUTICS, INC.

Patent Owner

Trial No. IPR2017-01621

Patent No. 9,358,240

DECLARATION OF MS. PILAR WYMAN

I, Pilar Wyman, hereby declare:

INTRODUCTION

1. I am a paid consultant for United Therapeutics Corporation in connection with two patent proceedings, IPR2017-01621 and IPR2017-01622. My compensation does not depend on the content of this declaration, the substance of any other testimony that I may offer in connection with this proceeding, or the disposition of this proceeding.

2. I am a professional freelance medical indexer and indexing consultant. My Curriculum Vitae describing my background and experience is provided as Ex. 2094. I have personal knowledge of the facts and opinions set forth in this declaration, which I believe to be true, and if called upon to do so, I would testify competently to them. In particular, as shown in my Curriculum Vitae, I have been involved in indexing medical publications for many years, as well as employed as a librarian. I was also lead consultant for the American Medical Association's *AMA Manual of Style, 10th edition* chapter 13, "Medical Indexes."

3. I am informed by counsel that a reference is considered "prior art" in these proceedings if it is publicly accessible and can be located prior to a certain date using reasonable diligence by a hypothetical person referred to as the person of ordinary skill in the "art" (which I will often refer to as a "POSA") or field to

which the patent pertains. I am further informed that, for these proceedings, the parties have offered two alternative definitions for a POSA:

- (a) a POSA at the time of invention would have been a person with a post-graduate degree in medicine or drug development (such as the pharmaceutical sciences) with at least two years of experience in the investigation or treatment of pulmonary hypertension. A POSA may also have had additional experience in the study, development, or use of dosage forms that had been used to treat pulmonary hypertension, such as solid oral dosage forms (e.g., tablets and capsules), injectables, and inhaled therapies. A POSA may have had a lower level of formal education if such a person had more years of experience in the investigation or treatment of pulmonary hypertension; and

- (b) according to Dr. Bennett (Ex. 1013, ¶¶ 12-13), a POSA holds a Ph.D. degree in pharmaceutical science or a related discipline like chemistry or medicinal chemistry, as well as at least two years of practical experience in the development of potential drug candidates, specifically in the delivery of drug by inhalation. I understand that this person according to his definition could have had a lower level of formal education than a Ph.D. degree if such a person had more years of experience in the

development of inhalable drugs. Also, according to Dr. Bennett's definition, this person would regularly review literature about pharmaceutical sciences and drug delivery and would know how to carry out library research using library resources to find out more information about areas being researched. In addition, this POSA would know how to evaluate potential drugs for their in vitro and in vivo activity and toxicity using tests disclosed in the relevant literature. Furthermore, because drug development involves a multidisciplinary approach, I understand that a POSA according to Dr. Bennett may interface or consult with individuals having specialized expertise, for example, a pharmacologist and/or physician with experience in the administration, dosing and efficacy of drugs for the treatment of a particular disease state.

These definitions of a POSA are interchangeable for purposes of my analysis.

4. I have reviewed the Declaration of Scott Bennett along with all of its attachments (Ex. 1013). I have also conducted some searches of PubMed (NLM) and American Heart Association Scientific Sessions in connection with preparing this Declaration and reviewed certain other exhibits identified below.

Document 1. Robert Voswinckel, et al. "Inhaled trepostinil sodium for the treatment of pulmonary hypertension" Abstract #1414, *Circulation*, 110, 17, Supplement (October 2004): III-295.

5. The first reference discussed in the Bennett Declaration is Voswinckel, an abstract that is contained in a 1102-page supplement to the journal *Circulation* in 2004 – specifically to vol. 110, issue 17 (Ex. 1013, 27-32). The Supplement, dated October 26, 2004, contains 1102 pages (Ex. 1013, 29), with the Voswinckel abstract appearing on page 295 (Ex. 1013, 32). According to Ex. 1013, the abstract was also presented at a meeting of the American Heart Association in New Orleans in Nov. 2004 (Ex. 1013, 27).

6. The Bennett Declaration asserts that this abstract would have been available by December 2004. Ex. 1013, 13-14. I do not agree with this conclusion for the following reasons. What is shown in the Bennett Declaration is an online entry from the British Library (Ex. 1013, 33):

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